

REMARKS

The pending Office Action addresses claims 61-69, 71-89, and 95. Applicant appreciates the Examiner's allowance of claims 72-75, and the Examiner's indication that claims 84-89 represent allowable subject matter. Remaining claims 61-69, 71, 76-84, and 95 stand rejected.

Amendments to the Claims

Applicant amends independent claim 84 to reorganize the claim language and to clarify that the insertion element is pulled into the stabilizing element. Support for this amendment can be found throughout the specification, for example, at page 12, lines 1-4. Applicant amends claim 85 to provide proper antecedent basis as suggested by the Examiner. Applicant amends independent claim 95 to specify that inserting the insertion element into the stabilizing element causes the stabilizing element to expand. Support for this amendment can be found throughout the specification, for example, at page 3, lines 21-24. No new matter is added.

Claim Rejections Pursuant to 35 U.S.C. §103

The Examiner rejects claims 61-69, 71, 75-84, and 95 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,870,957 of Goble et al. ("Goble") in view of U.S. Patent 5,725,529 of Nicholson et al. ("Nicholson").

Claims 61-69 and 71

Independent claim 61 recites a method for anchoring soft tissue within bone including drilling an opening into bone, inserting a stabilizing element into the bone opening, threading soft tissue through an aperture in an insertion element, and inserting the insertion element into the stabilizing element. A stem on the insertion element has a diameter greater than a diameter of an axial channel in the elongate sleeve of the stabilizing element such that the insertion element causes the stabilizing element to *deformably expand* and obtain a *pressure fit* within the bone opening.

Goble does not teach or even suggest a stem that causes a stabilizing element to *deformably expand* to obtain a *pressure fit* within a bone opening, and it would not have been obvious to modify Goble in view of Nicholson to have such a configuration because such a modification would render

Goble unsatisfactory for its intended purpose and would change the principal operation of Goble. MPEP 2143.01(V) states that “[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification,” and MPEP 2143.01(VI) states that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”

Goble discloses a ligament anchor system that includes a stud (10) having a ligament graft attached thereto, and a threaded footing (11) that receives the stud therein. In use, the threaded footing is threaded into a bone hole, and a mechanical interlock is used to mate the stud to the threaded footing. In particular, the stud has several cross-cuts formed therein that allow the stud to flex inwardly as it is inserted through the threaded footing, and to spring back out once it is fully inserted through the threaded footing. The stud does not expand to cause the threaded footing to deformably expand to obtain a pressure fit within the bone. Rather, a lip (16) formed on the distal end of the stud overlaps with the end of the threaded footing to retain the stud in the footing using a mechanical interlock.

The specific purpose of Goble is to provide an anchor that allows the tension on the ligament to be adjusted once implanted. This is repeated throughout the specification. For example, in the Summary of the Invention Goble states that a specific “object of the present invention is to provide a system where, after healing, tension on an installed ligament, ligament type device, with or without a stint, can be released . . .” Col. 1, lines 58-60. *See also*, Col. 2, lines 3-1. Goble later explains that once implanted, the tension of the ligament can be tested by moving the knee and, if adjustment is needed, the footing can be turned further into or out of the bone. *See, e.g.*, Col. 3, lines 30-34. The tension on the ligament can also be adjusted by cutting a portion of the stud flared end to allow the stud to slide within the footing. *See, e.g.*, Col. 3, lines 39-42.

If the stud of Goble were modified to have a size that is effective to deformably expand the threaded footing to obtain a pressure fit within bone, the anchor could not be used for its intended purpose and such a modification would change the principal operation of the device. In particular, if the threaded footing is deformably expanded by the stud, the tension on the ligament could not be

adjusted by turning the threaded footing further into or out of the bone, as threads on the threaded footing would be deformed and embedded in bone preventing removal. Moreover, the tension could not be adjusted by cutting the stud to allow it to slide within the threaded footing, as the stud would be maintained in a fixed position relative to the threaded footing. Accordingly, no person having ordinary skill in the art would modify the stud of Goble to have a size that allows the stud to deformably expand the threaded footing to obtain a pressure fit within bone.

Independent claim 61, as well as claims 62-69, and 71 which depend directly or indirectly therefrom, therefore distinguish over Goble and Nicholson and represent allowable subject matter.

Claims 75-83

Independent claim 75 recites a method for replacing a torn ligament including the steps of obtaining a tendon graft, drilling a hole into bone, looping the tendon graft through an aperture in an insertion element, inserting a stabilizing element into the bone hole, and inserting the insertion element into the stabilizing element. The insertion element includes a stem with an aperture-containing stem head and is held in the stabilizing element by a *compression fit*.

For similar reasons discussed above with respect to claim 61, it would not have been obvious to modify Goble to use a compression fit to hold the stabilizing element within a bone tunnel. Such a modification would render the device unsatisfactory for its intended purpose and would change the principal operation of the device. As discussed above, the sole purpose of the Goble anchor is to allow the tension on the ligament to be adjusted *after* the device is implanted. If the device is modified to use a compression fit, the threaded foot would be fixed within the bone and the tension on the ligament therefore could not be adjusted, thereby changing the principal operation of the device. Accordingly, independent claim 75, as well as claims 76-83 which depend directly or indirectly therefrom, distinguish over Goble and Nicholson and therefore represent allowable subject matter.

Claim 84

Independent claim 84 recites a method for replacing a torn ligament that includes obtaining a tendon graft, drilling a hole into bone, looping the tendon graft through an aperture in an insertion

element, inserting a stabilizing element into the bone hole, and pulling the insertion element in to the stabilizing element. The Examiner argues that the step of pulling the Goble device would have been considered obvious to an ordinary artisan if not inherent. Applicant respectfully disagrees.

It would not have been obvious to modify Goble to pull the stud into the threaded footing because such a modification would require almost all of the teachings of Goble to be ignored and the device to be substantially reconstructed and redesigned. The stud of Goble is specifically designed to be pushed into the threaded footing, and the stud does not include anything that would allow it to be pulled into the threaded footing. The flared end of the stud provides no location from which to pull the stud into the footing, and modifying the stud to include a feature that would allow the stud to be pulled into the stabilizing element would interfere with the operation of the stud. Accordingly, independent claim 84 distinguishes over Goble and Nicholson and therefore represents allowable subject matter.

Claim 95

Independent claim 95 recites a method for anchoring soft tissue within bone that includes drilling a stepped opening into bone, inserting a stabilizing element into the stepped bone channel by screwing the stabilizing element into the stepped bone opening by use of an emplacement device fitted into a non-cylindrical axial channel in the stabilizing element, threading soft tissue through an aperture in an insertion element having a stem with a diameter larger than the axial channel, and inserting the distal end of the insertion element into a proximal end of the stabilizing element to *expand* the stabilizing element.

For similar reasons discussed above with respect to claim 61, it would not have been obvious to modify the stem of Goble to have a size that allows it to *expand* the stabilizing element because such a modification would render the device unsatisfactory for its intended purpose and would change the principal operation of the device. Accordingly, independent claim 95 distinguishes over Goble and Nicholson and therefore represents allowable subject matter.

Conclusion

In view of the above amendments and remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

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